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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,772

07/06/2007

Misa Ochiai

47236-0011-00-US

1234

55694 7590 09/30/2008
DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,772	Applicant(s) OCHIAI ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9 in part and 10 in full, drawn to methods of producing strains of lipid-producing *Mortierella* fungi comprising the step of suppressing expression of a fatty acid elongase gene.

Group 2, claim(s) 1-9 in part and 11 in full, drawn to methods of producing strains of lipid-producing *Mortierella* fungi comprising the step of suppressing expression of a fatty acid desaturase gene.

Group 3, claims 12 and 13 in part, drawn to breeding kits for producing strains of lipid-producing *Mortierella* fungi comprising the step of suppressing expression of a fatty acid elongase gene.

Group 4, claims 12 and 13 in part, drawn to breeding kits for producing strains of lipid-producing *Mortierella* fungi comprising the step of suppressing expression of a fatty acid desaturase gene.

Group 5, claim 14 in part, drawn to lipid-producing *Mortierella* fungi in which expression of a fatty acid elongase gene is suppressed.

Group 6, claim 14 in part, drawn to a lipid producing *Mortierella* fungi in which expression of a fatty acid desaturase gene is suppressed.

Group 7, claim 15 in part, drawn to a method of producing polyunsaturated fatty acids from *Mortierella* fungi in which expression of a fatty acid elongase gene is suppressed.

Group 8, claim 15 in part, drawn to a method of producing polyunsaturated fatty acids from *Mortierella* fungi in which expression of a fatty acid desaturase gene is suppressed.

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Claims 1-9 are generic to inventions 1 and 2. Claims 12 and 13 are generic to inventions 3 and 4. Claim 14 is generic to inventions 5 and 6. Claims 15 is generic to inventions 7 and 8. Absent a showing that unity of invention exists, claims will be examined to the extent that they read on the elected invention.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The prior art taught methods of using *Mortierella* strains for producing lipids, wherein fatty acid desaturase activity was decreased by mutation or by use of specific enzyme inhibitors. See e.g. Certik et al (Trends in Biotechnology 16(12): 500-505, 1998, of record) and Shimizu et al (Oil Chemistry 42(4): 254-264, 1993, partial translation of record). The prior art also taught that enzyme activity could be inhibited by inhibiting expression of the gene encoding the enzyme, and taught methods of inhibiting gene expression through the use of antisense or dsRNA in a wide variety of organisms. See e.g. (Ueda (J. Neurogenetics 15(3-4): 193-204, 2001, of record), Nicolas et al (EMBO J. 22(15): 3983-3991, 2003, of record), Kennerdell et al (Cell 95: 1017-1026, 1998, of record), Ngo et al (PNAS 95: 14687-14692, 1998, of record), Wargelius et al BBRC 263: 156-161, 1999, of record). There is no evidence of record that would have suggested to one of ordinary skill in the art at the time of the invention that antisense and dsRNA gene expression approaches would not have functioned in *Mortierella*, and there existed means for delivering genetic material to *Mortierella* (see Mackenzie et al (App. Env. Microbiol. 66(1): 4655-4661, 2000)). Accordingly, the use of antisense or dsRNA gene suppression methods to inhibit fatty acid desaturase enzyme activity in *Mortierella* is considered to be an obvious variation of the existing methods of using specific enzyme inhibitors or loss-of-function mutants, and the claimed invention fails to make a contribution over the prior art, such that unity of invention is lacking. It is also noted that claim 1 is broad enough to read on methods of culturing any *Mortierella* species under conditions that would suppress expression of any gene, e.g. growth in rich media which might suppress the expression of amino acid biosynthetic pathway genes. Note that 37 CFR 1.475(b) does not allow for grouping of different statutory classes of invention (i.e. products, methods of use, and methods of making) where there is a lack of unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, James (Doug) Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Richard Schnizer, Ph. D./
Primary Examiner, Art Unit 1635